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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,353	07/23/2001	Mark Dehdashtian	VAS-5644	3388

7590 12/03/2002
Edwards Lifesciences LLC
Law Dept.
One Edwards Way
Irvine, CA 92614

EXAMINER

JACKSON, ANDRE K

ART UNIT PAPER NUMBER

2856

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,353

Applicant(s)

DEHDASHTIAN ET AL.

Examiner

Andre' K. Jackson

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 17 and 20 is/are rejected.
- 7) ☒ Claim(s) 8, 13-16, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
- 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
- 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: On page 8, line 27 "50" and "52"; line 30 "54a", "54b" and "56a". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,2,4-7,9-12,17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Bier et al.

Regarding claim 1, Vilendrer discloses a "High frequency intravascular prosthesis fatigue tester" which has pre-tester/tester with fixtures to couple the free ends of the tissue tube, a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. What is not disclosed by Vilendrer is an animal tissue tube. However, Bier et al. discloses "A new bioabsorbable intravascular stent: in vitro assessment of hemodynamic and morphometric characteristics" which has an animal tissue tube (Page 188, paragraph 4, line 2). Therefore, to modify Vilendrer to include an animal tissue tube as taught by Bier et al. would have been obvious to one of ordinary skill in the art at the time of invention since those are similar to the construction of humans.

Regarding claim 2, Vilendrer does not disclose where the animal tissue is porcine. However, Bier et al. discloses animal tissue that is swine, which is porcine. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer to include where the animal tissue is porcine since the tissue is close to human tissue.

Regarding claim 4, Vilendrer discloses a pulsatile pumping system for fluid supply that pressurizes the tissue tube lumen to pressures found in the human vascular system (Column 6, 46-54).

Regarding claim 5, Vilendrer discloses a sensor for measuring the exterior diameter of the tissue tube (Column 6, lines 30-45).

Regarding claim 6, Vilendrer discloses where the sensor is non-contact sensor (Column 3, line 64).

Regarding claim 7, Vilendrer discloses where sensor is a laser micrometer (Column 4, line 9).

Regarding claim 9, Vilendrer discloses where sealingly coupling opposed free ends of a tissue tube onto fixtures of a tester/pre-tester (Figure 3), positioning a stent within the tissue tube (Figure 6, column 4, line 35) and providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36), a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. What is not disclosed by Vilendrer is an animal tissue tube. However, Bier et al. discloses an animal tissue tube (Page 188, paragraph 4, line 2). Therefore, to modify Vilendrer to include an animal tissue tube as taught by Bier et al. would have been obvious to one of ordinary skill in the art at the time of invention since those are similar to the construction of humans.

Regarding claim 10, Vilendrer discloses pressurizing the fluid in the tissue tube lumen to pulsatile pressures found in the human vascular system (Column 2, 5-9).

Regarding claim 11, Vilendrer discloses measuring the exterior diameter of the tissue tube at different pressures (Column 6, line 54).

Regarding claim 12, Vilendrer discloses recording data (12) on the measured exterior diameter of the tissue tube, sealingly coupling opposed free ends of an tissue tube onto fixtures of a tester (Figure 3), positioning a stent within the tissue tube (Figure 6, column 4, line 35), providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36), pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54) and measuring the exterior diameter of the synthetic tube and controlling the fluid pressure based on the recorded data (Column 6, lines 4-19).

Regarding claim 17, Vilendrer discloses recording data (12) on the measured exterior diameter of the tissue tube, sealingly coupling opposed free ends of a tissue tube onto fixtures of a tester/pre-tester (Figure 3), positioning a stent within the tissue tube (Figure 6, column 4, line 35), providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36), pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54) and measuring the exterior diameter of the

synthetic tube and controlling the fluid pressure based on the recorded data (Column 6, lines 4-19).

Regarding claim 20, Vilendrer does not disclose where the tissue is animal tissue. However, Bier et al. discloses animal tissue that is swine. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer to include animal tissue since the tissue is in close relation to human tissue.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer in view of Bier et al. as applied to claim 1 above, and further in view of Love et al.

Regarding claim 3, Vilendrer nor Bier et al. discloses where the animal tissue is a section of porcine aorta with any side branches ligated. However, Love et al. discloses where the animal tissue a section of porcine (Column 1, lines 33-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Vilendrer to include where the animal tissue is a section of porcine as taught by Bier et al. since tissue is close to human tissue. Side branches are not disclosed but it would be within the purview of the skilled artisan to ligate the branches to prevent the any leakage.

6. Claims 8,13-16,18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andre' K. Jackson whose telephone number is (703) 305-1522. The examiner can normally be reached on Mon.-Fri. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are N/A for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1782.

A.J.
December 2, 2002


DANIEL S. LARKIN
PRIMARY EXAMINER